

**K033710 MR850 RESPIRATORY HUMIDIFIER, MODEL MR850JHU**Apr 13, 2004  
139 days to decisionK033710 · Product code: **BTT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k033710/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Nov 26, 2003
Decision date	Apr 13, 2004
Days to decision	139 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fisher &amp;Paykel Healthcare , Ltd.</b>
Location	Auckland, New Zealand, NZ
Contact	BRETT WHISTON
Website	<a href="https://www.fphcare.com/">https://www.fphcare.com/</a>
510(k) history	70 submissions · 70 cleared · 1988-2025

Fisher &Paykel Healthcare, Ltd. is a medical device manufacturer based in Auckland, New Zealand. The company has driven innovation in healthcare technologies for over 50 years. Fisher &Paykel Healthcare has received FDA 510(k) clearances from total submissions since 1988. The company specializes in Anesthesiology devices, which represent 91% of its regulatory submissions. The latest clearance was granted in 2025, confirming active ongoing development. Recent cleared devices include high-flow nasal therapy systems, noninvasive ventilation masks, and respiratory support int...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k033710/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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